

REMARKS/ARGUMENTS

Rejections under 35 U.S.C. §112, first paragraph

Claim 63 was rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

The Examiner contended that “claim 63 appears to be putting particle-filled layers over a stent that does not contain an active ingredient.” The Examiner added that “[w]hat would be the point of coating barrier layers if there were no active ingredient?”

Applicants respectfully disagree with the Examiner’s characterization of claim 63. The fact that claim 63 does not specifically recite an active ingredient does not mean that the stent coating cannot have an active ingredient. On the contrary, claim 63 can read on a stent coating that includes an active ingredient. For example, claim 63 reads on the embodiment shown in Figure 2C of the present application, which has a coating including an active ingredient. In Figure 2C, the coating (28A, 28B, 34A, 34B) includes a first region (28B, 34B) and a second region (28A, 34A), wherein each of the first and second regions includes particles (30A, 30B), and wherein the first region ((28B, 34B)) has a greater particle volume fraction as compared to the second region (28A, 34A). This example clearly shows that the coating of claim 63 can contain an active ingredient.

Applicants’ invention has several aspects, one of which is directed to the distribution of particles in a stent coating, to which claim 63 is directed. To this aspect of the invention, an active ingredient is not a critical or essential feature. Therefore, an active ingredient is not recited in claim 63. In fact, many stent coating method claims do not recite an active ingredient. (A cursory review of issued patents show that many stent coating method claims recite a coating but do not mention an active ingredient.) Similarly, in the area of automotive technology, for example, a claim directed to an automobile with an inventive frame need not recite a steering system or a brake, even though a steering system and a brake may be important to the operation of the automobile.

According to MPEP 2164.08(c) and 2172.01, to reject a claim on the ground that a claim element is missing is proper only when the language of the specification or a statement by Applicant makes it clear that the limitation is critical or essential for the invention. Since

the Examiner did not show that the specification or Applicants make it clear that the active ingredient limitation is critical or essential to the invention of claim 63, this rejection is improper.

The Examiner also contended that the limitation that “each of the first and second regions includes particles” is new matter. She further contended that page 39, line 22 to page 40, line 6 of the specification “merely requires that one region of the barrier layer have a greater particle volume fraction than a second region but does not require BOTH regions MUST contain particles.”

Applicants respectfully disagree with the Examiner’s contention. The limitation that “each of the first and second regions includes particles” is clearly supported by the application as originally filed. For example, Figure 2C shows that each of the two regions has particles, which are designated by reference numeral 30A or 30B. Additionally, the particles (30A, 30B) in the two regions are described in the first fully paragraph on page 40 of the specification, which is the paragraph just below the paragraph cited by the Examiner.

Rejection under 35 U.S.C. §112, Second Paragraph

Claim 63 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner contended that “[i]t is not clear what the relationship is of the two regions – are they adjacent?” For the following reasons, the rejection is respectfully traversed.

As stated above, according to MPEP 2164.08(c) and 2172.01, a claim rejection based on an allegedly missing claim element is proper only when the language of the specification or a statement by Applicants makes it clear that the limitation is critical or essential for the invention. Since the Examiner did not show that the specification or Applicants made it clear that the relationship between the two regions is critical or essential to the invention of claim 63, this rejection is improper.

It should be noted that the fact that the physical relationship between the regions is not specified in claim 63 does not make claim 63 indefinite. It simply means that the relationship is not critical or essential to the invention of claim 63. If Applicants had specified the relationship in claim 63, a competitor could have easily designed around claim

63. For example, if Applicants had specified that the regions in claim 63 are adjacent, a competitor could have easily designed around claim 63 by slightly separating the two regions, thereby rendering claim 63 meaningless.

Objection to the Specification

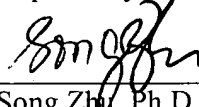
The specification was objected to as not properly indicating the use of trademarks and trade names. Applicants believe that the amendments to the specification overcome the objection.

In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. No. 07-1850.

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